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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,011	10/25/1999	MICHAEL SIMONS	BIS-043/CIP	1306

7590 10/08/2003

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MAGNOLIA, MA 01930

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/08/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,011

Applicant(s)

SIMONS ET AL.

Examiner

Roy Teller

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to Paper No: 28, received 7/28/03, in which applicant withdrew claims 13-14, and amended claim 11.

Claims 11 and 12 are pending.

Applicant has discussed in detail several points of contention concerning the prosecution of the application. The examiner refers applicant to Paper No: 25 and 27 for reasoning in examiner's decisions.

Claim Rejections - 35 USC § 102

The rejection under 35 U.S.C. 102(b) of claims 11 and 12 is withdrawn pursuant to applicant's arguments.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:4; peptide PR-11(experiment # 6, page 46 of the instant specification); who individually causes a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, does not reasonably provide enablement for a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide less than 26 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. In view of the above, those skilled in the art are unlikely to accept the data as being correlatable to SEQ ID NO:3, a 15 amino acid residue and a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide less than 26 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro_pro-X-X-Pro where X is any amino acid; being

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able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. Therefore, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT
1654
10/7/03
RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER